

05/26/00

**UTILITY
PATENT APPLICATION
TRANSMITTAL**

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	BSC-035CN
First Named Inventor	Gellman et al.
Title	BONE ANCHORS FOR BONE ANCHOR IMPLANTATION DEVICE

530 U.S. 579909
5/26/00

APPLICATION ELEMENTS		ADDRESS TO: Box Patent Application Assistant Commissioner for Patents Washington, D.C. 20231
1. <input checked="" type="checkbox"/> Fee Transmittal Form		ACCOMPANYING APPLICATION PARTS
2. <input checked="" type="checkbox"/> Specification and Drawings [Total Pages 15] - Specification - (10 pages) - Claims - (2 pages) - Abstract - (1 page) - Sheets of Drawings - (2 sheets)		7. <input type="checkbox"/> 37 CFR 3.73(b) Statement (when there is an assignee) <input type="checkbox"/> Power of Attorney
		8. <input type="checkbox"/> English Translation Document (<i>if applicable</i>)
		9. <input type="checkbox"/> Information Disclosure Statement (IDS)/PTO-1449 <input type="checkbox"/> Copies of IDS Citations
3. <input checked="" type="checkbox"/> Oath or Declaration [Total Pages] a. <input type="checkbox"/> Newly executed (original) b. <input checked="" type="checkbox"/> Copy from a prior application (37 CFR 1.63(d)) <i>(for continuation/divisional with Box 17 completed)</i> <i>[Note Box 4 below]</i>		10. <input type="checkbox"/> Preliminary Amendment <input type="checkbox"/> Drawings [Total Sheets] <input type="checkbox"/> Letter to Official Draftsperson Including Drawings [Total Pages]
		11. <input checked="" type="checkbox"/> Return Receipt Postcard
4. <input checked="" type="checkbox"/> Incorporation by Reference (usable if Box 3b is checked) The entire Disclosure of the prior application, from which a copy of the oath or declaration is supplied under Box 3b, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.		12. <input type="checkbox"/> Small Entity Statement(s) <input type="checkbox"/> Statements filed in prior application, (Status still proper and desired)
5. <input type="checkbox"/> Microfiche Computer Program (<i>Appendix</i>)		13. <input type="checkbox"/> Certified Copy of Priority Document(s)
6. <input type="checkbox"/> Nucleotide and/or Amino Acid Sequence Submission <input type="checkbox"/> Computer Readable Copy <input type="checkbox"/> Paper Copy (identical to computer copy) <input type="checkbox"/> Statement verifying identify of above copies		14. <input type="checkbox"/> Deletion of Inventor(s) Signed statement attached deleting inventor(s) named in the prior application.
17. <input type="checkbox"/> If a CONTINUING APPLICATION, check appropriate box and supply the requisite information: <input checked="" type="checkbox"/> Continuation <input type="checkbox"/> Divisional <input type="checkbox"/> Continuation-in-part (CIP) of prior application Serial No. <u>09/238,663</u> . Priority to the above application(s) is claimed under 35 U.S.C. 120. Prior application information: Examiner: <u>Ho, U.</u> Group/Art Unit: <u>3731</u> .		15. <input checked="" type="checkbox"/> Patent Application Data Entry Form
18. <input type="checkbox"/> Priority - 35 U.S.C. 119 <input type="checkbox"/> Priority of application Serial No. filed on _____ in the U.S. Patent Office is claimed under 35 U.S.C. 119. <input type="checkbox"/> The certified copy has been filed in prior U.S. application Serial No. _____/_____ on _____. <input type="checkbox"/> The certified copy will follow.		16. <input type="checkbox"/> Other:
CORRESPONDENCE ADDRESS		SIGNATURE BLOCK
Direct all correspondence to: Patent Administrator Testa, Hurwitz & Thibeault, LLP High Street Tower 125 High Street Boston, MA 02110 Tel. No.: (617) 248-7000 Fax No.: (617) 248-7100		<p>Respectfully submitted,</p> <p><i>[Signature]</i></p> <p>John V. Forcier Attorney for the Applicants Testa, Hurwitz & Thibeault, LLP High Street Tower 125 High Street Boston, MA 02110</p>

Inventor Information

Inventor One Given Name :: Barry N.
Family Name :: Gellman
Name Suffix ::
Postal Address Line One :: 19 Pebblebrook Road
Postal Address Line Two ::
City :: North Easton
State/Province :: Massachusetts
Country :: U.S.A.
Postal or Zip Code :: 02356
City of Residence :: North Easton
State/Prov. of Residence :: Massachusetts
Country of Residence :: U.S.A.
Citizenship :: U.S.A.

Inventor Two Given Name :: David J.
Family Name :: Sauvageau
Name Suffix ::
Postal Address Line One :: 147 Old Ferry Road
Postal Address Line Two ::
City :: Methuen
State/Province :: Massachusetts
Country :: U.S.A.
Postal or Zip Code :: 01844
City of Residence :: Methuen
State/Prov. of Residence :: Massachusetts
Country of Residence :: U.S.A.
Citizenship :: U.S.A.

Correspondence Information

Correspondence Customer Number :: 021323

Application Information

Title Line One :: Bone Anchors for Bone Anchor Implantation Device
Title Line Two ::
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Formal Drawings :: Y
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Docket Number :: BSC-035CN
Licensed - U S Government Agency ::
Contract Number ::
Grant Number ::
Secrecy Order in Parent Application ::

Representative Information

Representative Customer Number :: 021323

Continuity Information

This application is a :: Claims Benefit
>Application One :: 60/072,639
Filing Date :: January 27, 1998

This application is a :: Continuation of
>>Application Two :: 09/238,663
Filing Date :: January 26, 1999

PATENT APPLICATION
Atty. Docket No.: BSC-035

Bone Anchors For Bone Anchor Implantation Device

Cross Reference to Related Applications

5 This application claims priority to and the benefit of U.S. Provisional Patent Application Serial No. 60/072,639 filed January 27, 1998. The entirety of this priority document is hereby incorporated by reference.

Technical Field

This invention relates to various bone anchor designs for use in a bone 10 anchor implantation device.

Background Information

Urinary incontinence, the inability to control urination from the bladder, is a widespread problem that affects people of all ages. Urinary incontinence is more prevalent in women than in men. Urinary incontinence in women is typically 15 causes by intrinsic sphincter deficiency (ISD), a condition in which the valve of the urethral sphincter do not properly coapt, or by hypermobility, a condition in which the muscles around the bladder relax, causing the bladder neck and proximal urethra to rotate and descend in response to increases in intraabdominal pressure. Hypermobility may be the result of pregnancy or other conditions which weaken 20 the muscles. Urinary incontinence in men can be caused by post radical prostatectomy, which destroys the valves of the urethral sphincter. Urinary incontinence can also be caused by birth defects, disease injury, aging and urinary tract infection.

Numerous approaches for treating urinary incontinence are available. One treatment is a surgical operation to return the bladder and proximal urethra to their normal anatomical positions by elevating them in order to reduce intraabdominal pressure. There are also noninvasive procedures for stabilizing and/or slightly compressing the urethra so as to prevent the leakage of urine. For example, a stabilizing or compressive force may be applied by sutures passing through the soft tissue surrounding the urethra or, alternatively, may be applied by means of a sling suspended by sutures. In some procedures bone anchors are inserted in the pubic bone or symphysis pubis in order to anchor the suture to the bone. Often an anchor receiving hole is drilled into the bone prior to inserting the anchor. Other bone anchor devices incorporate a drill for predrilling an opening in the bone thus eliminate the need for a predrilling step.

Summary of the Invention

The present invention relates to a bone anchor implantation device for driving a bone anchor into the bone by the application of a retrograde force. More particularly, the present invention relates to improved bone anchors. Bone anchor configurations according to the invention reduce the amount of force required to secure the bone anchor into a bone anchor implantation site.

Bone anchors are often attached to bones in order to provide support for a “sling” useful in improving or maintaining a patient’s urinary incontinence. In one procedure, a suture carrying anchor is driven through the vaginal wall and into the posterior portion of the pubic bone or symphysis pubic, and the suture(s) attached to the bone anchor(s) extend through the vaginal wall and may be attached to the endopelvic fascia, the vaginal wall, a sling, or other material to stabilize and/or slightly compress the urethra thereby improving the patient’s urinary incontinence. The present invention effectively addresses concerns in affixing an anchor to bone or tissue.

The present invention is directed to a bone anchor which implants into the bone and supports a suture. The bone anchor, which releasably engages to a bone anchor implantation device, comprises a generally cone-shaped head with at least two, preferably three, cutting edges which come together to form a pointed tip at 5 the end of the anchor that first contacts the target site. The cutting edges on the generally cone-shaped head can be defined by flat planar surfaces or outward curved surfaces. These bone anchor configurations reduce the amount of force and pressure that a user (i.e. a surgeon) of a bone anchor implantation device must apply to implant the bone anchor into the bone.

10 In general, one aspect of the present invention involves a bone anchor for use with a bone anchor implantation device. The bone anchor comprises a generally cone-shaped head which has a wide end, a narrow end, and at least two cutting edges. At the narrow end of the generally cone-shaped head, the cutting edges come together to form a pointed tip. The wide end of the head can 15 releasably engage to a bone anchor implantation device.

Embodiments of this aspect of the invention can include the following features. The cutting edges can be defined by flat surfaces or curved surfaces. The cutting edges can be formed in various ways such as by cutting or scalloping the surface of the bone anchor. Also, the cutting edges can be sharp edges. In a 20 preferred embodiment, there are three cutting edges which come together to form the pointed tip at the narrow end.

In an alternative embodiment, the bone anchor further comprises a collar member for retaining the bone anchor in place. The collar member is coupled to the wide end of the generally cone-shaped head. The bone anchor can also 25 comprise a shaft with an eyelet for receiving a suture. The shaft is coupled to the wide end of the generally cone-shaped head.

In general, another aspect of the invention relates to a bone anchor implantation device comprising a handle having a proximal and a distal end, a hooked-shaped shaft, a bone anchor mount attached at the distal end of the shaft

and a bone anchor releasably engaged to the bone anchor mount. The bone anchor comprises a generally cone-shaped head with a wide end which engages to the bone anchor mount, a narrow end, and at least two cutting edges which come together to form a pointed tip at the narrow end. The bone anchor can have 5 various configurations, such as cutting edges defined by flat or curved surfaces. The bone anchor is inserted into a bone by applying a retrograde force to the bone anchor implantation device.

The foregoing and other objects, aspects, features, and advantages of the invention will become more apparent from the following description and from the 10 claims.

Brief Description of the Drawings

In the drawings, like reference characters generally refer to the same parts throughout the different views. Also, the drawings are not necessarily to scale, emphasis instead generally being placed upon illustrating the principles of the 15 invention.

Figure 1 is a side view of a bone anchor according to the invention with curved surfaces defining the cutting edges.

Figure 2 is another view of the bone anchor according to the invention of Figure 1.

20 Figure 3 is a side view of a bone anchor according to the invention with flat cutting edges.

Figure 4 is another view of the bone anchor of Figure 3.

Figure 5 is a side view of a bone anchor according to the invention having a generally cone-shaped head with cutting edges and a collar member.

25 Figure 6 is a side view of a bone anchor implantation device with a hook-shaped shaft.

Description

A bone anchor according to the invention has a generally cone-shaped head with a wide end, a narrow end, and at least two cutting edges which come together to form a pointed tip at the narrow end of the head. The bone anchor is utilized in 5 a bone anchor implantation device. The various bone anchor configurations of the present invention reduce the amount of force required to drive the bone anchor into the bone.

Representative bone anchors are illustrated in Figures 1-4. The bone anchors 22 comprise a generally cone-shaped head 14 which is able to pierce and 10 securely engage the bone, and the bone anchors 22 generally require less force than conventional bone anchors to drive them into bone. The generally cone-shaped head 14 has a wide end 18, a narrow end 19, and at least two cutting edges 26 which come together to form a pointed tip 24 at the narrow end 19. The generally cone-shaped head 14 is coupled to a shaft portion 16. The shaft portion 15 16 of the bone anchor 22, which is generally cylindrical in shape, can be releasably engaged to a bone anchor implantation device 28. Only a portion of the device 28 is shown in Figures 1-5.

The generally cone-shaped head 14 of the bone anchor 22 is located at an end of the shaft portion 16 opposite the end which attaches to the bone anchor 20 implantation device 28. The apex of the generally cone-shaped head is a point 24 which is suitable for piercing and being driven into bone. The diameter of the generally cone-shaped head 14 increases in the longitudinal direction from the point 24 towards the shaft portion 16.

As shown in Figures 1-4, the generally cone-shaped head 14 of the bone 25 anchor 22 has at least two, preferably three or more, cutting edges 26. The cutting edges 26 can extend the length of the generally cone-shaped head 14, and they come together at the point 24. Preferably, the cutting edges are sharp. The cutting edges reduce the amount of force that is necessary to implant the bone anchor into the bone.

In some embodiments, such as that shown in Figures 1 and 2, the cutting edges 26 on the bone anchor 22 are defined by curved or scalloped surfaces 25 formed in the anchor 22. These surfaces 25 are cut into the generally cone-shaped head 14. These arcuate surfaces 25 form and define the cutting edges 26 and they generally extend from the wide end 18 of the generally cone-shaped head 14 to the narrow end 19 of the generally cone-shaped head 14.

In other embodiments such as that shown in Figures 3 and 4, the cutting edges 16 on the bone anchor 22 are defined by flat surfaces 23 formed in the anchor 22. The flat surfaces 23 are cut into the generally cone-shaped head 14.

10 The flat surfaces 23 extend generally from the wide end 18 to the narrow end 19 of the generally cone-shaped head 14.

Preferably, the generally cone-shaped head 14 is formed integrally with the shaft portion 16 of the bone anchor 22. Alternatively, the generally cone-shaped head 14 and the shaft portion 16 may initially be formed separately and then 15 subsequently attached to one another.

Any known materials suitable for orthopedic anchor devices may be employed to construct the bone anchor 22 of the present invention. Preferably, the bone anchor 22 is formed from a metallic material possessing sufficient strength to penetrate the bone. Such materials include titanium 316 LVM stainless steel, 20 CoCrMo alloy, Nitinol alloy, or other suitable materials. In a preferred embodiment, the bone anchor is formed from titanium.

Another embodiment of a bone anchor according to the invention is illustrated in Figure 5. The bone anchor 22 of Figure 5 comprises a generally cone-shaped head 14 which is able to pierce and securely engage bone. The generally 25 cone-shaped head 14 is coupled to a shaft portion 16 with an oval eyelet 18 therethrough for receiving and holding one or more suture strands. To retain the generally cone-shaped head 14 within the bone, the bone anchor 22 further comprises a collar member 20. The collar member 20 is used for retaining the

bone anchor 22 in place, once it has been driven into the bone, by lodging within the bone in a manner to resist removal of the bone anchor 22.

The shaft portion 16 of the bone anchor 22 is generally cylindrical in shape and has the eyelet 18, or bore, formed radially therethrough proximate one 5 of its ends. The eyelet 18 may be oval, round, or other suitable shape and is of a sufficient size to permit one or more suture strands to pass therethrough. The circumference of each outer end of the eyelet 18 is chamfered or grounded to provide a bevel portion 22. It should be appreciated that the bevel portion 22 provides a generally smooth surface for contacting suture strand which has been 10 passed through the eyelet 18. The eyelet 18 is located on the shaft portion 16 of the bone anchor 22 such that the transverse axis of the eyelet 18 intersects the longitudinal axis of the bone anchor 22.

The generally cone-shaped head 14 of the bone anchor 22 is located at an end of the shaft portion 16 opposite the end having the eyelet 18. The apex of the 15 generally cone-shaped head 14 is a point 24 which is suitable for piercing and being driven into bone. The diameter of the generally cone-shaped head 14 increases along a longitudinal direction from the point 24 towards the eyelet 18.

As discussed above with reference to Figures 1-4, the bone anchor 22 has at least two, preferably three or more cutting edges 26. The cutting edges 26 are 20 preferably sharp. In the disclosed embodiment in Figure 5, the cutting edges 26 are defined by curved or scalloped surfaces.

The collar member 20 is rotatably fitted over the shaft portion 16 to form the assembled bone anchor 22 as shown in Figure 5. While there is no need to permanently secure the collar member 20 to the generally cone-shaped head 14, 25 the collar member 20 may nevertheless be securely attached to the generally cone-shaped head 14. It will be appreciated, however, that by permitting the generally cone-shaped head 14 to rotate freely with respect to collar member 20, a suture strand can be rotated by the surgeon after implantation to a position where the

forces acting on the suture strand by the bone anchor 22 are more evenly distributed around the region of the shaft portion 16 adjacent to the eyelet 18.

In addition, it should also be appreciated that the two-piece construction of the bone anchor affords machining advantages over a single-piece bone anchor.

- 5 That is, it is easier to machine each of these two components (i.e., the collar member 20 and the bone anchor 22, where the bone anchor 22 includes the head 14 and the shaft portion 16) separately and subsequently to assemble them together, as opposed to machining the same basic structural features from a single piece of material

- 10 Another aspect of the invention is a bone anchor implantation device comprising a hooked-shaped shaft with a bone anchor mount adapted to releasably engage at the distal end of the shaft a bone anchor with at least two cutting edges. The bone anchor mount generally points toward the handle, such that the user can drive the bone anchor into the bone by simply pulling back on the handle and using
- 15 the patient's body weight to provide an opposing force. Preferably, the longitudinal axis of the bone anchor mount is aligned with the longitudinal axis of the handle.

A representative bone anchor implantation device having a hooked elongated member and a bone anchor with cutting edges are shown in Figure 6.

- 20 The bone anchor implantation device 210 has a handle 212 having a proximal end 214 and a distal end 216. The handle 212 may be made of a variety of materials, such as plastic or metal. The elongated member 220 may be made of a variety of materials such as stainless steel, engineering plastics, fiber-bearing components, or other materials. Preferably, the elongated member 220 is made of stainless steel.

- 25 In the embodiment of the bone anchor implantation device 210 shown in Figure 6, the elongated member 220 comprises a straight proximal section 222, a first generally curved section 224 distal to the straight proximal section, a second generally curved section 226 distal to the first curved section, a third generally curved section 228 distal to the second curved section, and a fourth generally

curved section 230 distal to the third curved section. However, one of skilled in the art would appreciate that the elongated member 220 could also comprise a series of straight segments angled relative to one another to form a hook.

5 The straight proximal section 222 of the elongated member 220 has an annular shoulder 232 which abuts the distal end 216 of the handle. The straight proximal section 222 passes through a lumen (not shown) extending through the handle. The proximal end of the straight proximal section 222 has a threaded bore which is adapted to receive a screw 236 which secures the elongated member 220 to the handle.

10 The handle 212 defines an axis at the proximal end of the anchor implantation device 210, and then moving distally from the handle 212 the elongated member 220 first curves away from the axis of the handle and then back toward the axis of the handle 212. The distal end of the elongated member 220 preferably is located in the vicinity of the axis of the handle 212. In some preferred 15 embodiments, the elongated member 220 at the distal end can be generally perpendicular to the axis of the handle or can actually be curving back toward the handle 212.

20 A bone anchor mount 238 for releasably engaging a bone anchor 248 is attached to the distal end 240 of the fourth curved section 230 of the elongated member 220. Preferably, the bone anchor mount 238 is oriented at an angle of approximately 90° relative to the distal end 240 of the fourth curved section 230, as illustrated in Figure 6.

25 A variety of bone anchors can be releasably engaged to the bone anchor implantation device. In accordance with the invention, the bone anchor used with the device 210 is a bone anchor 248 having a generally cone-shaped head and cutting edges as described above with respect to Figures 1-5.

The bone anchor mount 238 is oriented so that the bone anchor 248 is pointed in the general direction of the handle 212. In one embodiment, the axis of

the bone anchor 248 is generally aligned with the axis of the handle 212, with the bone anchor pointed toward the handle 212.

The bone anchor mount 238 may be fabricated from the same materials as the elongated member 220 and may be attached to the elongated member 220 by a
5 variety of methods such as brazing.

Although this invention has been described in terms of certain preferred embodiments, other embodiments which will be apparent to those of ordinary skill in the art in view of the disclosure herein are also within the scope of this invention. Accordingly, the scope of the invention is intended to be defined only
10 by reference to the appended claims.

What is claimed is:

CLAIMS

- 1 1. A bone anchor for use with a bone anchor implantation device
- 2 comprising a generally cone-shaped head having a wide end, a narrow end,
- 3 and at least two cutting edges wherein said cutting edges come together to
- 4 form a pointed tip at the narrow end.

- 1 2. The device of claim 1 wherein the cutting edges of the head are
- 2 defined by at least one flat surface.

- 1 3. The device of claim 1 wherein the cutting edges of the head are
- 2 defined by at least one curved surface.

- 1 4. The device of claim 1 wherein the head has three of the cutting
- 2 edges.

- 1 5. The device of claim 1 wherein the cutting edges comprise sharp
- 2 edges.

- 1 6. The device of claim 1 wherein said bone anchor comprises titanium.

- 1 7. The device of claim 1 further comprising a collar member disposed
- 2 near the wide end of the head.

- 1 8. The device of claim 1 further comprising a shaft with an eyelet for
- 2 receiving a suture, the shaft being coupled to the wide end of the head.

- 1 9. A device for inserting a bone anchor into a bone, comprising:
- 2 a handle having a proximal end and a distal end,
- 3 a hook-shaped shaft having a first and second end, said first end
- 4 being connected to the distal end of said handle,
- 5 a bone anchor mount connected to the second end of said shaft, and

6 a bone anchor releasably engaged to the bone anchor mount, the
7 bone anchor comprising a generally cone-shaped head with a wide end, a
8 narrow end, and at least two cutting edges wherein the cutting edges come
9 together to form a pointed tip at the narrow end.

Bone Anchors For Bone Anchor Implantation Device

Abstract of the Disclosure

Bone anchors and bone anchor implantation devices can be used to maintain or improve urinary continence by suspending or stabilizing the bladder neck of a patient. The bone anchors have a generally cone-shaped head with two or more cutting edges which reduce the amount of force required to implant the bone anchor into bone.

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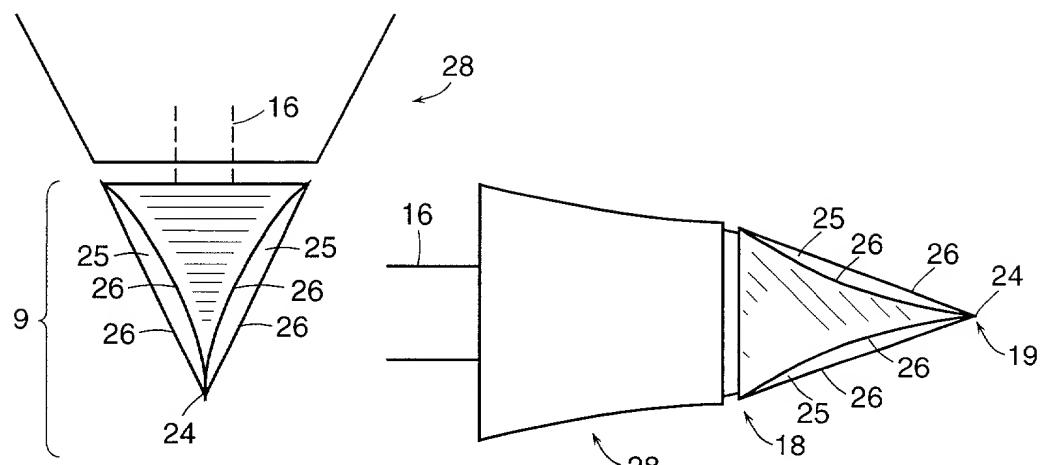


FIG. 2

FIG. 1

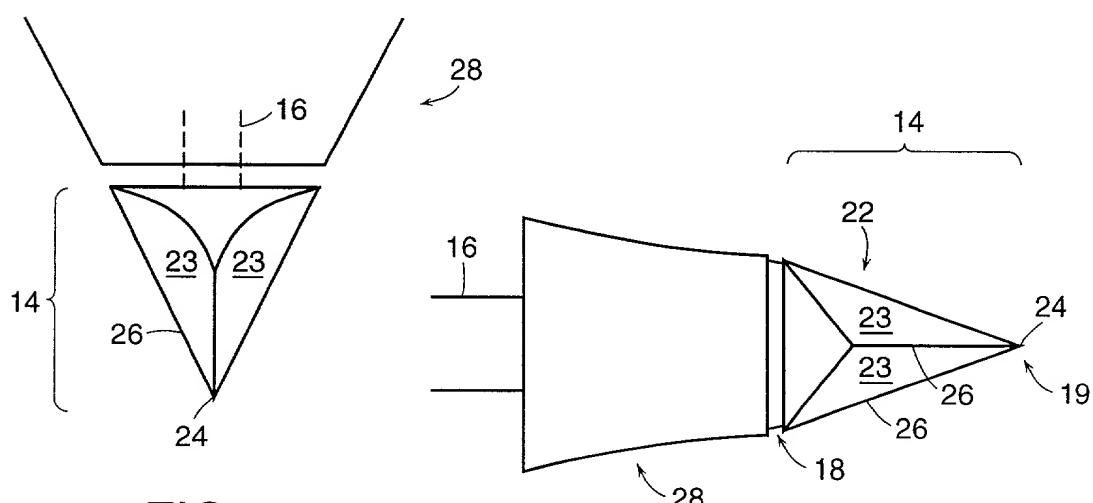
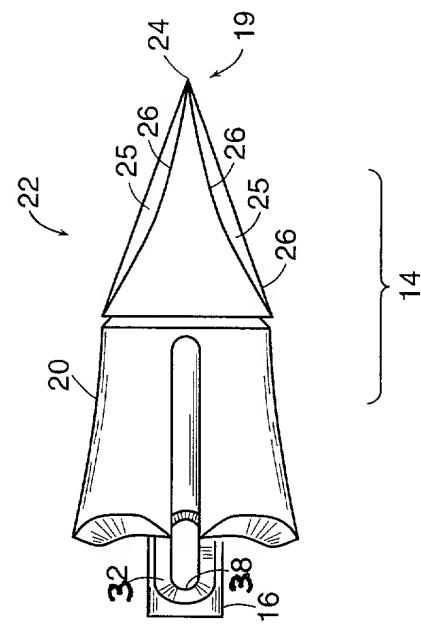
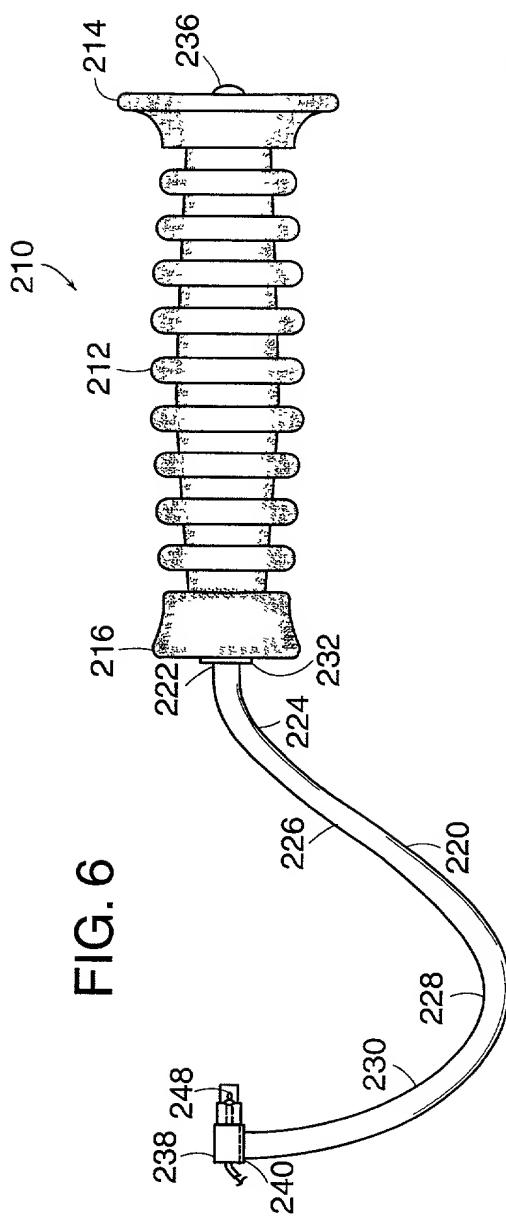


FIG. 4

FIG. 3



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COPY

DECLARATION AND POWER OF ATTORNEY FOR UTILITY OR DESIGN PATENT APPLICATION		Attorney Docket No.	BSC-035
		First Named Inventor	Gellman et al.
COMPLETE IF KNOWN			
		Application Serial Number	09/238,663
		Filing Date	January 26, 1999
		Group Art Unit	Not yet assigned.
		Examiner Name	Not yet assigned.

As a below named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

BONE ANCHORS FOR BONE ANCHOR IMPLANTATION DEVICE

(Title of the Invention)

the specification of which

is attached hereto

OR

was filed on January 26, 1999 as United States Application Serial Number or PCT International (MM/DD/YYYY)

Application Number 09/238,663 and was amended on (MM/DD/YYYY) (*if applicable*).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached?
			<input type="checkbox"/>	YES <input type="checkbox"/> NO <input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
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			<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>

Additional foreign application numbers are listed on a supplemental priority data sheet attached hereto.

I hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below.

Application Serial Number(s)	Filing Date (MM/DD/YYYY)	
60,072,639	01/27/98	<input type="checkbox"/> Additional provisional application serial numbers are listed on a supplemental priority data sheet attached hereto.

Declaration and Power of Attorney for Utility or Design Patent Application

Serial No.: 09/238,663

Page 2 of 3

DECLARATION - Utility or Design Patent Application

I hereby claim the benefit under 35 U.S.C. 120 of any United States application(s), or 365(c), of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. 112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

U.S. Parent Application or PCT Parent Serial Number	Parent Filing Date (MM/DD/YYYY)	Parent Patent Number (if applicable)

Additional U.S. or PCT international application numbers are listed on a supplemental priority data sheet attached hereto.

As a named inventor, I hereby appoint the following registered practitioners to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith: Customer Number →

OR

Registered practitioner(s) name/registration number listed below

Name	Registration Number	Name	Registration Number
Steven M. Bauer	31,481	Kurt W. Lockwood	40,704
Isabelle A.S. Blundell	43,321	Marianne McLaughlin	42,870
Michael H. Brodowski	41,640	Thomas C. Meyers	36,989
Jennifer A. Camacho	P-43,526	Joseph B. Milstein	42,897
Joseph A. Capraro, Jr.	36,471	Ronda P. Moore	P-44,244
Jerrie L. Chiu	41,670	Edmund R. Pitcher	27,829
John J. Cotter	38,116	Kurt Rauschenbach	40,137
Jennifer L. Dupré	41,722	Michael A. Rodriguez	41,274
John V. Forcier	42,545	Michael J. Schmelzer	43,093
Duncan A. Greenhalgh	38,678	J. Scott Southworth	39,382
William G. Guerin	41,047	Christopher W. Stamos	35,370
Ira Heffan	41,059	Robert J. Tosti	35,393
Danielle L. Herritt	P-43,670	Thomas A. Turano	35,722
Elizabeth E. Kim	43,334	Michael J. Twomey	38,349
Douglas J. Kline	35,574	Christine C. Vito	39,061
John D. Lanza	40,060	Patrick R.H. Waller	41,418
Timothy P. Linkkila	40,702		

Additional registered practitioners named on supplemental Registered Practitioner Information sheet attached hereto.

Direct all correspondence to:

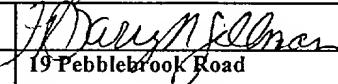
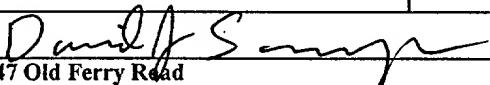
Patent Administrator
TESTA, HURWITZ & THIBEAULT, LLP
High Street Tower
125 High Street
Boston, MA 02110
Tel. No.: (617) 248-7000
Fax No.: (617) 248-7100

Declaration and Power of Attorney for Utility or Design Patent Application

Serial No.: 09/238,663

Page 3 of 3

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Name of Sole or First Inventor:		<input type="checkbox"/> A petition has been filed for this unsigned inventor						
Given Name (first and middle [if any])				Family Name or Surname				
Barry N.				Gellman				
Inventor's Signature						Date		
Residence	19 Pebblebrook Road					Citizenship	U.S.A.	
Post Office Address	19 Pebblebrook Road							
	City	North Easton	State	MA	Zip	02356	Country	U.S.A.
<input type="checkbox"/> Additional inventors are being named on the _____ supplemental Additional Inventor(s) sheet(s) attached hereto.								
Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor						
Given Name (first and middle [if any])				Family Name or Surname				
David J.				Sauvageau				
Inventor's Signature						Date		
Street Address	147 Old Ferry Road					Citizenship	U.S.A.	
Post Office Address	147 Old Ferry Road							
	City	Methuen	State	MA	Zip	01844	Country	U.S.A.
Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor						
Given Name (first and middle [if any])				Family Name or Surname				
Inventor's Signature						Date		
Street Address						Citizenship		
	City		State		Zip		Country	
Post Office Address								
	City		State		Zip		Country	